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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/924,946	08/08/2001	Mark J. Evans	0630/1G703US2	3104

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EXAMINER
WILSON, MICHAEL C

ART UNIT	PAPER NUMBER
1632	9

DATE MAILED: 12/11/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/924,946	EVANS ET AL.
	Examiner	Art Unit
	Michael C. Wilson	1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-46* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7, 40 and 41, drawn to a lysyl oxidase polypeptide (EER-7) or a fragment thereof, classified in class 435, subclass 183.

II. Claims 8-14 and 17-20, drawn to nucleic acids encoding EER-7, host cells comprising a vector encoding EER-7 and a method of making EER-7 using host cells in culture, classified in class 536, subclass 23.1, et al.

III. Claim 15, drawn to an animal transformed with a vector encoding EER-7, classified in class 800, subclass 13.

IV. Claims 21 and 22, drawn to an antibody that recognizes EER-7 and a method of detecting EER-7 using said antibody, classified in class 530, subclass 387.1.

V. Claims 23-25, drawn to a method of detecting EER-7 expression by detecting mRNA encoding EER-7, classified in class 435, subclass 6.

VI. Claims 26-29 and 42-44, drawn to cells transfected with DNA encoding different estrogen receptors, classified in class 435, subclass 325.

VII. Claims 30-39, drawn to a method of identifying compounds using cells transfected with DNA encoding different estrogen receptors and detecting EER-7 expression by detecting mRNA encoding EER-7, classified in class 435, subclass 6.

VIII. Claim 45, drawn to a knockout, non-human animal in which EER-7 expression is suppressed, classified in class 800, subclass 13.

IX. Claim 46, drawn to a non-human animal comprising a vector encoding a protein that regulates EER-7, classified in class 800, subclass 13.

The inventions are distinct, each from the other because of the following reasons:

Groups I and II are patentably distinct because the protein can be used to isolate antibodies while the nucleic acid can be used a probe. The protocols and reagents required for proteins and DNA are materially distinct and separate. The protein does not require the nucleic acid and the nucleic acid does not require the protein.

Groups I and III are patentably distinct because the protein can be used to isolate antibody while the animal can be used to determine the effect of EER-7 overexpression *in vivo*. The protocols and reagents for proteins and animals are materially distinct and separate. The protein does not require the animal and the animal does not require the protein.

Groups I and IV are patentably distinct because the protein functions as an enzyme while the antibody functions as part of the immune system. The protocols and reagents required for proteins and antibodies are materially distinct and separate. The protein does not require the antibody and the antibody does not require the protein.

Groups I and V are patentably distinct because the protein can be used to isolate antibodies while the method can be used to identify compounds that alter EER-7 expression. The protocols and reagents required for proteins and methods of detecting

mRNA are materially distinct and separate. The protein does not require the method and the method does not require the protein.

Groups I and VI are patentably distinct because the protein can be used to isolate antibodies while the cells can be used to identify compounds that alter EER-7 expression. The protocols and reagents required for proteins and transfected cells are materially distinct and separate. The protein does not require the cells and the cells do not require the protein.

Groups I and VII are patentably distinct because the protein can be used to isolate antibodies while the method is used to identify compounds that alter EER-7 expression. The protocols and reagents required for proteins and transfected cells are materially distinct and separate. The protein does not require the cells and the cells do not require the protein.

Groups I and VIII are patentably distinct because the protein can be used to isolate antibodies while the knockout can be used to identify the function of EER-7 expression *in vivo*. The protocols and reagents required for proteins and knockout animals are materially distinct and separate. The protein does not require the knockout and the knockout does not require the protein.

Groups I and IX are patentably distinct because the protein can be used to isolate antibodies while the transgenic can be used to identify the function of the protein that regulates EER-7 expression *in vivo*. The protocols and reagents required for proteins and transgenic animals are materially distinct and separate. The protein does not require the transgenic and the transgenic does not require the protein.

Groups II and III are patentably distinct because the nucleic acids can be used as a probe while the animal can be used to determine the effect of EER-7 overexpression *in vivo*. The protocols and reagents for nucleic acids and animals are materially distinct and separate. The nucleic acids do not require the animal. The nucleic acids can be used to make patentably distinct products, such as probes, vectors, cells expressing EER-7, knockout animals in which EER-7 expression is suppressed or transgenic animals in which EER-7 is overexpressed.

Groups II and IV are patentably distinct because the nucleic acids can be used as a probe while the antibody can be used to isolate protein. The protocols and reagents required for nucleic acids and antibodies are materially distinct and separate. The nucleic acids do not require the antibody and the antibody does not require the nucleic acids.

Inventions II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can also be used to make protein. The process can also be performed using an antibody.

Groups II and VI are patentably distinct because the nucleic acids can be used as a probe while the cells can be used to identify compounds that alter EER-7 expression. The protocols and reagents required for the nucleic acids encoding EER-7 and transfected cells encoding different estrogen receptors are materially distinct and

separate. The nucleic acid encoding EER-7 does not require the cells and the cells do not require the nucleic acid encoding EER-7.

Groups II and VII are patentably distinct because the nucleic acids can be used as a probe while the method is used to identify compounds that alter EER-7 expression. The protocols and reagents required for nucleic acids encoding EER-7 and for transfected cells encoding different estrogen receptors are materially distinct and separate. The nucleic acids do not require the cells and the cells do not require the nucleic acids.

Groups II and VIII are patentably distinct because the nucleic acids can be used as a probe while the knockout can be used to identify the function of EER-7 expression *in vivo*. The protocols and reagents required for nucleic acids and knockout animals are materially distinct and separate. The nucleic acid does not require the knockout and the knockout does not require the nucleic acids - the knockout has a disruption in the EER-7 gene but the nucleic acids in Group II express.

Groups II and IX are patentably distinct because the nucleic acids can be used as a probe while the transgenic can be used to identify the function of the protein that regulates EER-7 expression *in vivo*. The protocols and reagents required for nucleic acids encoding EER-7 and transgenic animals expressing a protein that regulates EER-7 are materially distinct and separate. The nucleic acid encoding EER-7 does not require the transgenic and the transgenic does not require the nucleic acid encoding EER-7.

Groups III and IV are patentably distinct because the transgenic animal overexpressing EER-7 can be used to determine the effect of EER-7 overexpression *in vivo* while the antibody can be used to isolate protein. The protocols and reagents required for transgenics and antibodies are materially distinct and separate. The transgenics do not require the antibody and the antibody does not require the transgenics.

Groups III and V are patentably distinct because the transgenic animal overexpressing EER-7 can be used to determine the effect of EER-7 overexpression *in vivo* while the method is used detect EER-7 expression using mRNA. The protocols and reagents required for transgenics and the method are materially distinct and separate. The transgenics do not require the method and the method does not require the transgenics.

Groups III and VI are patentably distinct because the transgenic animal overexpressing EER-7 can be used to determine the effect of EER-7 overexpression *in vivo* while the cells can be used to identify compounds that alter EER-7 expression. The protocols and reagents required for the transgenic animal overexpressing EER-7 and transfected cells encoding different estrogen receptors are materially distinct and separate. The transgenic overexpressing EER-7 does not require the cells and the cells do not require the transgenic.

Groups III and VII are patentably distinct because the transgenic animal overexpressing EER-7 can be used to determine the effect of EER-7 overexpression *in vivo* while the method is used to identify compounds that alter EER-7 expression. The

protocols and reagents required for transgenics overexpressing EER-7 and for transfected cells encoding different estrogen receptors are materially distinct and separate. The transgenics do not require the cells and the cells do not require the transgenics.

Groups III and VIII are patentably distinct because the transgenic animal overexpressing EER-7 can be used to determine the effect of EER-7 overexpression *in vivo* while the knockout can be used to identify the effect of EER-7 suppression *in vivo*. The protocols and reagents required for transgenics overexpressing EER-7 and having a knockout of EER-7 are materially distinct and separate. The trasngenic overexpressing EER-7 does not require the knockout of EER-7 and the knockout of EER-7 does not require the transgenic overexpressing EER-7.

Groups III and IX are patentably distinct because the transgenic animal expressing EER-7 can be used to determine the effect of EER-7 overexpression *in vivo* while the transgenic expressing a protein that regulates EER-7 expression can be used to identify the function of the protein that regulates EER-7 expression *in vivo*. The protocols and reagents required for transgenics overexpressing EER-7 and transgenics overexpressing a protein that regulates EER-7 are materially distinct and separate. The transgenics overexpressing EER-7 do not require the transgenic overexpressing a protein that regulates EER-7 expression and the transgenic overexpressing a protein that regulates EER-7 expression does not require the transgenic overexpressing EER-7.

Groups IV and V are patentably distinct because the antibody can be used to isolate EER-7 while the method is used detect EER-7 expression using mRNA. The protocols and reagents required for antibodies and the method of detecting mRNA are materially distinct and separate. The antibodies do not require the method and the method does not require the antibodies.

Groups IV and VI are patentably distinct because the antibody can be used to isolate EER-7 while the cells can be used to identify compounds that alter EER-7 expression. The protocols and reagents required for antibodies and transfected cells encoding different estrogen receptors are materially distinct and separate. The antibodies do not require the cells and the cells do not require the antibodies.

Groups IV and VII are patentably distinct because the antibody can be used to isolate EER-7 while the method is used to identify compounds that alter EER-7 expression. The protocols and reagents required for antibodies and for transfected cells encoding different estrogen receptors are materially distinct and separate. The antibodies do not require the cells and the cells do not require the antibodies.

Groups IV and VIII are patentably distinct because the antibody can be used to isolate EER-7 while the knockout can be used to identify the effect of EER-7 suppression *in vivo*. The protocols and reagents required for antibodies and an EER-7 knockout animal are materially distinct and separate. The antibodies do not require the knockout of EER-7 and the knockout of EER-7 does not require the antibodies.

Groups IV and IX are patentably distinct because the antibody can be used to isolate EER-7 while the transgenic expressing a protein that regulates EER-7

expression can be used to identify the function of the protein that regulates EER-7 expression *in vivo*. The protocols and reagents required for antibodies and transgenics overexpressing a protein that regulates EER-7 are materially distinct and separate. The antibodies do not require the transgenic overexpressing a protein that regulates EER-7 expression and the transgenic overexpressing a protein that regulates EER-7 expression does not require the antibodies.

Groups V and VI are patentably distinct because the purpose of the method of group V is to detect the presence of EER-7 expression while the cells can be used to identify compounds that alter EER-7 expression. The protocols and reagents required for the method of Group V and the transfected cells encoding different estrogen receptors of Group VI are materially distinct and separate. The method does not require the cells and the cells do not require the method.

Groups V and VII are patentably distinct because purpose of the method of Group V is to detect the presence of EER-7 expression while the method of Group VII is to identify compounds that alter EER-7 expression. The protocols and reagents required for the method of Group V and VII are materially distinct and separate. The method of Group V does not require the method of Groups VII and the method of Group VII does not require the method of Group V.

Groups V and VIII are patentably distinct because the method of Group V is to detect the presence of EER-7 expression while the knockout can be used to identify the effect of EER-7 suppression *in vivo*. The protocols and reagents required for detecting the presence of EER-7 expression and an EER-7 knockout animal are materially distinct

and separate. The method does not require the knockout of EER-7 and the knockout of EER-7 does not require the method.

Groups V and IX are patentably distinct because the method of Group V is to detect the presence of EER-7 expression while the transgenic expressing a protein that regulates EER-7 expression can be used to identify the function of the protein that regulates EER-7 expression *in vivo*. The protocols and reagents required for detecting EER-7 expression and transgenics are materially distinct and separate. The methods do not require the transgenic and the transgenic does not require the method.

Inventions VI and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used in estrogen binding assays *in vitro*.

Groups VI and VIII are patentably distinct because the cells can be used to identify compounds that alter EER-7 expression while the knockout can be used to identify the effect of EER-7 suppression *in vivo*. The protocols and reagents required for identifying compounds that alter EER-7 expression and an EER-7 knockout animal are materially distinct and separate. The cells do not require the EER-7 knockout and the EER-7 knockout does not require the cells.

Groups VI and IX are patentably distinct because the cells can be used to identify compounds that alter EER-7 expression while the transgenic expressing a protein that

regulates EER-7 expression can be used to identify the function of the protein that regulates EER-7 expression *in vivo*. The protocols and reagents required for identifying compounds that alter EER-7 expression using cells transfected with different estrogen receptors and transgenics overexpressing a protein that regulates EER-7 expression are materially distinct and separate. The cells do not require the transgenic and the transgenic does not require the cells.

Groups VII and VIII are patentably distinct because the method can be used to identify compounds that alter EER-7 expression while the knockout can be used to identify the effect of EER-7 suppression *in vivo*. The protocols and reagents required for identifying compounds that alter EER-7 expression and an EER-7 knockout animal are materially distinct and separate. The method does not require the EER-7 knockout and the EER-7 knockout does not require the method.

Groups VII and IX are patentably distinct because the method can be used to identify compounds that alter EER-7 expression while the transgenic expressing a protein that regulates EER-7 expression can be used to identify the function of the protein that regulates EER-7 expression *in vivo*. The protocols and reagents required for identifying compounds that alter EER-7 expression using cells transfected with different estrogen receptors and transgenics overexpressing a protein that regulates EER-7 expression are materially distinct and separate. The methods do not require the transgenic and the transgenic does not require the method.

Groups VIII and IX are patentably distinct because the EER-7 knockout can be used to identify the effect of EER-7 suppression *in vivo* while the transgenic

expressing a protein that regulates EER-7 expression can be used to identify the function of the protein that regulates EER-7 expression *in vivo*. The protocols and reagents required for an EER-7 knockout and transgenics overexpressing a protein that regulates EER-7 expression are materially distinct and separate. The knockout does not require the transgenic and the transgenic does not require the knockout.Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group I-IX is not required for any other Group, restriction for examination purposes as indicated is proper.

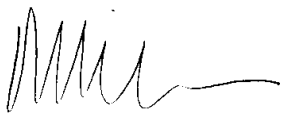
Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson whose telephone number is 703-305-0120. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on 703-305-4051. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Michael C. Wilson